K120995

DEC 0 3 2012

Section 5: **510(k) Summary**

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Date Prepared: October 5, 2012

Classification Name: System, Image Processing, Radiological

Common Name: PACS

Proprietary Name: eRAD PACS and eRAD RIS/PACS

Predicate Devices: eRAD PACS- #K061421(July 25, 2006)

Device Description:

eRAD PACS/ eRAD RIS/PACS Software Product is a PACS system, comprised of acquisition components, a central systems manager component, diagnostic viewing components, and an archiving component. The data flow is such that patient and procedure information is optionally delivered to the central system manager, followed by the acquisition of the image objects directly from the image sources or by one of the acquisition components. After receiving the procedure information or after receiving image objects, the central system manager searches for and retrieves relevant prior procedure data from the archiving a component. When the central system manager registers the acquired image objects and the retrieved prior procedure data, a user can access the information by selecting the item from the operator worklist. The image data is

transmitted to and rendered on the user's workstation using the diagnostic viewing components. After using the workstation to view the images, the user optionally dictates a report into the system, after which, a user can play back the diction and transcribe it to text. Once eRAD PACS's central system manager registers a report, the report is available for access by the referring physician, or it can be exported into an information system. At some configured point in time, the image data and the report information is delivered to the archiving component for backup and long-term storage.

Intended Use:

eRAD PACS/ eRAD RIS/PACS is a PACS software product used to receive DICOM images, scheduling information and textual report, organize and store them in an internal format, and to make that information available across a network via web and customized user interfaces.

The eRAD PACS/ eRAD RIS/PACS viewer software is intended for use as a primary diagnostic and analysis tool for diagnostic images. eRAD PACS/ eRAD RIS/PACS is for hospitals, imaging centers, radiologists, reading practices and any user who requires and is granted access to patient image, demographic and report information.

The eRAD PACS/ eRAD RIS/PACS viewer displays images from CT, computed radiography, MRI, mammography, nuclear medicine, PET, secondary capture, ultrasound, x-ray angiography, x-ray fluoroscopy and visible light modalities.

Lossy compressed mammography images and digitized film screen mammography images must not be reviewed for primary image interpretations. Mammography images may only be interpreted using an FDA approved monitor that offers at least 5 mega-pixel resolution and meets other technical specifications reviewed and accepted by FDA.

Substantial Equivalence:

The modifications to the eRAD PACS/ eRAD RIS/PACS Software do not alter the fundamental scientific technology of the device. The only modification made to the predicate device is making the software available to the user in a software-only option.

Discussion of Non-Clinical Testing Performed:

Thorough non-clinical system verification and validation testing was conducted in accordance with applicable international standards and internal design requirement to verify that the eRAD PACS/ eRAD RIS/PACS Software Product meet user needs and indications for use. Testing demonstrated that the eRAD PACS/ eRAD RIS/PACS Software Product were substantial equivalent to their predicate devices.

Conclusions:

The information provided in this premarket notification submission has shown that the eRAD PACS/ eRAD RIS/PACS Software Product is substantially equivalent to the predicate devices and are safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

eRAD, Inc.
% Ms. Jillian M Reed
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December 3, 2012

Re: K120995
Trade/Device Name: eRAD PACS/eRAD RIS/PACS Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 8, 2012
Received: October 9, 2012

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris, M.S.
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **#K120995**

Device Name: eRAD PACS/ eRAD RIS/PACS Software

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Prescription Use XX (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of in-vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

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